



September 28, 2004

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-16

Animal and Plant
Health Inspection
Service

Subject: Efficacy Requirements and Label Claims for Bovine Rotavirus Vaccine

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

Center for Veterinary
Biologics

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I. PURPOSE

This notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics policy concerning efficacy requirements and label claims for Bovine Rotavirus Vaccine.

II. BACKGROUND

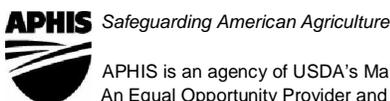
Infection with bovine rotavirus, most commonly group A rotavirus, can cause diarrhea in neonatal calves. Among the bovine group A rotavirus, eight glycoprotein (G) serotypes have been reported. Although the most commonly recognized G serotypes are G6 and G10, there have been reports of other G serotypes isolated from diarrheic calves in the United States and other parts of the world. The cross-protection provided by these serotypes is known to be very limited. This notice clarifies the type of label claims that can be made for rotavirus vaccines, and the efficacy data needed to support these label claims.

III. POLICY

Label claims may only be made for those G serotypes where protection has been demonstrated by satisfactory vaccination-challenge studies in calves. The primary variable should be diarrhea. Fecal shedding of rotavirus may be considered as a secondary variable. Firms should provide data confirming that the cause of post-challenge diarrhea was the challenge virus, ruling out other bacterial and viral enteropathogens. All licenses issued subsequent to October 31, 2004, for products containing bovine rotavirus should conform to this guideline. Labels and promotional materials for previously licensed products should be amended, as necessary, by October 31, 2005.

/s/ Richard E. Hill, Jr.

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Director
Center for Veterinary Biologics



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